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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/295,302	04/21/99	SCHMIDT	K 000007.00148

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EXAMINER	
GUPTA, A	
ART UNIT	**PAPER NUMBER**
1653	12

DATE MAILED: 10/04/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/295,302	Schmidt
Examiner	**Group Art Unit**
ANISH GUPTA	1653

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-7* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-7* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *11*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Improper Multiple Dependant Claims

1. Claims 6-7 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to claims in the alternative only. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

Second Paragraph

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "structural component", "recruiting component", and "growth and/or maturation component." However, it is unclear as to what constituents comprise each of the components.

In claim 2-5, applicants are requested deleted the word characterized since it is unclear if the carriers are present within the compositions.

Claim 1 recites the active ingredient is complex is coated. However, it is unclear what is to be "coated." Is the active ingredient coated or the organ or is the active ingredient itself coated?

Claim 1 state "reproduction of biological parts, especially organs for living being in which a carrier with an active ingredient complex is coated or which contains an active ingredient complex." However it is unclear what contains the active ingredient complex.

In claim 1, living being should be living beings.

Regarding claims 6-7, the word "means" is preceded by the word(s) "of the" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified

by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

First Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for method of stimulating the formation of bones, does not reasonably provide enablement for any other organ. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to enable the invention commensurate in scope with these claims.

The claims are drawn to a means for production or reproduction of biological parts especially organs by, presumably, coating the organ in a living being. However, the disclosure fails to provide any guidance for the production or reproduction of vital organs such as the heart, liver, lungs etc. . . . It is well established in the art that organs such as the heart and liver cannot be reproduced by the administration of an "active ingredient complex." The disclosure fails to provide any guidance, in the way of working examples or literal disclosure, of how the active ingredient complex can be used for the production or reproduction of any organ. The disclosure only indicates the reproduction and production of bone and not organs such as the heart, liver, lungs etc . . . As an illustration, the art has recognized the ineffectiveness of therapeutics on the regeneration of motor neurons after a CNS injury. Both references of Labes et al. And Tetzlaff et al. state that neurons confined within the CNS do not regenerate after axonal injury.

With respect to the production or reproduction of organ beyond bones, Applicants specification is similar to the disclosure discussed in *Ex parte Sudilovsky*, [sic] 21 U.S.P.Q2d 1702 (BPAI 1991) where it was held that the disclosure was non-enabling since:

> "[t]he specification, though highly detailed, is devoted solely to a description of compounds stated to be known ACE inhibitors. The remainder of the specification is directed to how to make tablets and solutions for injection. Any disclosure regarding utility is confined to broad allegations and suggestions without

> substantiating working example. As stated in In re Glass, 492 F.2d 1228, 181 USPQ 31, 35 (CCPA 1974), 'the strong feeling one gets from reading the entire specification is that either appellant did not have possession of the details of a single operative process or, if he did, he chose not to divulge them.'"

Similarly, Applicants specification discloses compositions that can be used for the formation of bones. However, the disclosure, with regard to method of producing or reproducing organs such as heart, liver, and brain, is confined to broad allegations and suggestions without substantiating working examples. Although working examples are not necessary in the specification, lack of a working example, however, are a factor to be considered. When a patent applicant chooses to forego exemplification and bases utility on broad terminology and general allegations, he runs the risk that unless one with ordinary skill in the art would accept the allegations as obviously valid and correct, the examiner may, properly, ask for evidence to substantiate them. *In re Novak*, 306 F.2d 924, 134 USPA 335 (CCPA 1962) 4; *In re Fouche*, 439 F.2d 1237, 169 USPQ 429 (CCPA 1971). In this case, the disclosure has not provided evidence of record of compositions that could be utilized to reproduce organs and the art has indicated that at least one organ, CNS neurons, do not regenerate, undue experimentation would be required to practice the claimed invention.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 5,830,859. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The claims of the instant application are drawn to a production or reproduction of biological parts by using a complex comprising on structural component, recruiting component, adhesion component, and a growth and/or

maturation component. Note that the recruiting component is defined as a chemotactic substance (page 1 of the instant specification).

The claims of the US Patent claims a method of stimulating the formation of bone in a maxillary sinus by utilizing a composition comprising a bone derived protein complex with some chemotaxis component, bond derived structural and adhesive component, and a bond derived growth or maturation component. The components claimed in the US Patent are similar to the components claimed in the instant application. The difference between the US Patent and the instant application is that the US Patent does not teach the treatment of osteoporosis, bone defects etc. . . However, since the US Patent claims that the composition is useful for the stimulating bone formation, it would have been obvious the composition could be used for the treatments claimed in the instant applications.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can normally be reached on (703)308-2923. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Christopher S. F. Low

Anish Gupta

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